

### REMARKS

This amended reply is in response to the Office communication dated June 20, 2007, in which the Examiner found that Applicant's reply filed on April 9, 2007, was not fully responsive to the Office Action dated October 13, 2006. In that office action claims 39-46 are rejected. Claims 39-46 are presented for examination, of which, claim 39 is independent in form.

Applicant acknowledges the Examiner's withdrawal of the objection of the drawings. Applicant also acknowledges the Examiner's withdrawal of the rejection of claims 39-46 under 35 U.S.C. § 112(2). However, the Examiner has indicated that new grounds of rejection are made. Applicant addresses the Examiner's new grounds of rejection below.

### Priority

The examiner finds that claims 39-46 are not entitled to priority to the earlier filed related applications, Application Nos. 07/010631 to 09/924275, because the claims do not find support in the manner provided by the first paragraph of 35 U.S.C. § 112. Applicant respectfully traverses. The paragraphs of a patent specification are not discreet capsules of disclosure, each to be dissected and interpreted in isolation, as if each is entirely self-supporting in defining a discrete aspect of the invention. Rather, the specification (Background, Summary, Description, Claims and Drawings) is to be taken in total for what it conveys to the person of ordinary skill in the art when considered as a whole. Indeed, claim terms are read in the context of the entire patent. *See Ortho-McNeil Pharma., Inc. v. Caraco Pharma. Labs., Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005)).

In this regard, Application No. 09/076,520, filed May 12, 1998, now U.S. Patent No. 6,287,331<sup>1</sup> discloses multiple metal layers as required by the claimed subject matter.

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<sup>1</sup> The present application, U.S. Application No. 10/751,749, filed on Jan. 5, 2004, is a continuation of Application No. 09/924,275, filed on Aug. 8, 2001, now abandoned, which is a continuation of Application No. 09/076,520, filed on May 12, 1998, now Pat. No. 6,287,331, which is a continuation of Application No. 08/955,268, filed on Oct. 21, 1997, now Pat. No. 6,290,721, which is a continuation Application No. 08/282,776, filed on Jul. 29, 1994, now

In various embodiments, the metals used in the filament and their configuration are selected to exhibit various desirable characteristics....”

“... In some cases, if desirable, the inner and outer **metals may be the same metal** or metals of the same elemental composition that are different metals because of e.g., different crystal structure or other properties.

In other embodiments of elastic filament members, **the outer member is formed of a continuous solid mass of a highly elastic biocompatible metal ....”**

The core material is preferably a continuous solid mass, but may also be in a powder-form. **Typically, the core includes a metal** that is relatively dense to enhance radiopacity.... Preferably, the core metal has a low modulus of elasticity.... Generally, a smaller difference between the modulus of elasticity between the outer material and core results in a smaller variation of the modulus from that of the outer material in the filament of the invention....

The outer member and core may be in many cross-sectional geometric configurations, such as circular, square, triangular, hexagonal, octagonal, trapezoidal and the geometrical configuration of the core may differ from that of the longitudinal member. For example, the outer member of a filament may be rectangular in cross-section with a rectangular core or triangular or hexagonal in cross-section with a circular core. A stent filament may also take on the form of tubing with a lumen within the core extending along the axis. **A stent filament may also include successive layers of less dense outer material and more dense core material to form a multi-composite system of three layers or more from exterior to center.** The core may extend intermittently along the axis in a desired pattern.

(U.S. Patent No. 6,287,331; column 6, line 41 through column 7, line 67.) The above paragraphs are consistent with paragraphs 0038-0042 of the present application.

And in the present application, in asserting the lack of priority from Applicants' earlier applications, the Examiner focuses exclusively on the fourth sentence of paragraph [0042], relying on the fact that the word "metal" does not appear in that paragraph. But from even the brief segment of the Description above, when considered in full, it is readily apparent that the reference by Applicant to a multi-composite system of three layers or more clearly conveys that the layers are layers of metal. There is no supportable basis for any other conclusion (notwithstanding the Examiner's reference back to paragraph [0029] for the parenthetical mention that "(The surface 7 may include a non-metal coating of, e.g. fluorocarbons, silicones, hydrophilic and lubricious biocompatible materials.)"). At no point does Applicant characterize the surface coatings as "layers." It is further apparent from the above disclosure that one or more of the metal layers may be the same metal.

In light of the above remarks, the subject matter as previously presented is entitled to a filing date of at least July 8, 1992. Applicants request the objection be reconsidered and withdrawn.

Objections Under 35 U.S.C. § 132(a)

In the office action of October 13, 2006 the Examiner objected to the amendment filed August 8, 2006 under 35 U.S.C. § 132(a) alleging that the amendment introduced new matter into the disclosure. Applicant respectfully disagrees. The introduction of "the third metal layer is formed of said first metal" in claim 40 is clearly supported in paragraphs 0038-0042 of the present application, as discussed above with regard to Applicant's claim of priority. Applicant requests the objection be withdrawn with regard to claim 40.

The Examiner also asserts that a "third metal layer" is not sufficiently disclosed with regard to claims 39-46. Again, as discussed above, paragraphs 0038-0042 of the present application disclose embodiments having inner and outer materials of the same metal or different metals, wherein the core includes a metal and the outer member may be a biocompatible metal. Furthermore, "A stent filament may also include successive layers of less dense outer material and more dense core material to form a multi-composite system of three layers or more from exterior to center." ((U.S. Patent Application Pub. No. 2004/0138740, at ¶¶ 38-42). As such,

Applicant submits that the third metal layer is disclosed in the present application as least for the reasons discussed above and requests the rejection be withdrawn.

The Examiner also objects to a third metal associated with a sheet as claimed in claim 46. The Examiner asserts that the disclosure of a third layer is directed to a filament. But paragraph 44 of the published application discloses various embodiments including a stent in the form of a metal member “configured as other than a filament-form, e.g., a composite sheet form member in the form of a cuff or tube.” (U.S. Patent Application Pub. No. 2004/0138740, at ¶44). As such, a third metal layer associated with a sheet is disclosed and applicant requests the objection be withdrawn.

#### Claim Rejections – 35 U.S.C. § 112

Claims 39-46 are rejected under the first paragraph of 35 U.S.C. § 112 for the same reason that the Examiner objected to Applicant’s claim of priority, discussed above. From paragraphs 38-42 of the present application it is readily apparent that the reference by Applicant to a multi-composite system of three layers or more clearly conveys that the layers are layers of metal. Applicant requests that the rejection be withdrawn.

Claims 39-46 are also rejected under the second paragraph of 35 U.S.C. § 112 for omitting the necessary structural cooperative relationship in the order of layers. Applicant notes that an inventor is not limited to claiming only implementations of the invention described as “preferred” but rather are entitled to claim their invention(s) as broadly in scope as permitted by the prior art. *See Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 93 F.3d 1572, 1582 n. 7 (Fed.Cir.1996)(“A claim is ordinarily not limited to the preferred embodiment described in the specification”). In the present application, in support of the claimed scope of claim 39, Examiner is directed to the following disclosure:

“[0007] In the invention, metal such as in the form of wire or filament or the like is used for constructing tubular medical endoprostheses such as stents. Desirable attributes of these wires vary with the stent application, but include properties such as stiffness, tensile strength, elasticity, radiopacity, weldability, flexural life, conductivity, etc. These properties are hard to find in

conventional wires. According to the invention, **desired properties are achieved by creating a multiple metal coaxial construction**. For example, it may be very desirable to have high radiopacity along with elasticity and strength. This is **accomplished by combining a radiopaque metal with an elastic metal. Although it is possible to put either metal on the inside or outside**, it is preferable to put the dense radiopaque material (e.g., tantalum) on the inside (core) since dense materials are generally less elastic and the elastic material (e.g., titanium or nickel-titanium alloy) on the outside (clad). The clad or "skin" of the wire will undergo more deformation in bending than the core, so the elastic component is best positioned at the skin.

(U.S. Patent Application Pub. No. 2004/0138740, at ¶7) (emphasis added). Here Applicant discloses embodiments of the invention in addition to an ordering of the first through third layers such that the density increases toward the core. Applicant requests that the rejection be withdrawn.

#### Double Patenting

Claim 39 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 23 of U.S. Patent No. 6,287,331. Applicant requests that this rejection be held in abeyance until the claim is found otherwise allowable.

#### Claim Rejections – 35 U.S.C. § 102

Claims 39-44 are rejected as unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,387,123 (Jacobs). As discussed above the claimed subject matter is entitled to a priority date of at least July 8, 1992. Therefore, Jacobs is not prior art to the claimed subject matter and the rejection should be withdrawn.

#### Claim Rejections – 35 U.S.C. § 103

Claims 45 and 46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobs. But as discussed above, Jacobs is not prior art to the claimed subject matter and the rejection should be withdrawn.

Claims 39-42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,197,978 (Hess). Claims 39-42 recite an implantable medical stent including a metal member having a cross-sectional thickness of at least 0.0075 inch or less formed of at least two different metals, a first metal layer, a second metal layer, and a third metal layer, wherein the density of the second metal is greater than the density of the first metal and the second metal enhances the radiopacity of the metal member.

The Examiner maintains the rejection asserting that the previous official notice is admitted prior art. The Examiner states that Hess remains silent as to the thickness of the stent wall and that it is admitted prior art that it was common knowledge to make the stent of the wall as thin as possible on the order of 0.005 inch and would have been obvious to one of ordinary skill in the art at the time the invention was made to make the wall of Hess on the order of thickness of about 0.005 inch. But the Examiner's conclusion that the official notice is now admitted prior art is improper because the Applicant invited the Examiner to provide evidence of the level of common knowledge in the art and rebutted the Examiner's rejection based on the unsupported statement of common knowledge. Moreover, the Examiner improperly relied on the unsupported statement of common knowledge to bridge a gap in the teaching of Hess when there is no motivation in Hess to do so.

The Examiner states that the previous official notice relating to stent wall thicknesses is now considered admitted prior art because Applicant failed to rebut the Examiner's official notice by not specifically pointing out the errors in the Examiner's action.

MPEP § 2144.03 provides:

"If applicant does not seasonably traverse the well known statement during examination, then the object of the well known statement is taken to be admitted prior art. In re Chevenard, 139 F.2d 71, 60 USPQ 239 (CCPA 1943). A seasonable challenge constitutes a demand for evidence made as soon as practicable during prosecution. Thus, applicant is charged with rebutting the well known statement in the next reply after the Office action in which the well known statement was made.

In this regard Applicant points to page 9 of the August 21, 2006 Amendment, in which Applicant invited the Examiner to support the official notice and rebutted the Examiner's obviousness rejection. Applicant previously argued:

...As acknowledged by the Examiner, Hess does not disclose the thickness of a metal member, and there is no suggestion to modify Hess's stent to have the claimed cross-sectional thickness other than the Examiner's official notice, to which Applicant does not concede.... As a result one having ordinary skill in the art would not have been motivated to modify Hess's stent to arrive at the claimed subject matter.

(August 21, 2006 Amendment in Reply to Action of Feb. 3, 2006, pg. 9). By clearly stating that the Applicant did not concede to the Examiner's official notice, Applicant was inviting the Examiner to provide support, as required. Indeed, the Board of Patent Appeals and Interferences, in Ex Parte Ji-Young Lee, Appeal No. 2006-2328 (Feb. 23, 2007) recently stated that an examiner may "take notice of facts beyond the record which, while not generally notorious, are capable of such instant and unquestionable demonstration as to defy dispute." *Id.*, (citing In re Ahlert, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (1970). Moreover, "Assertions of technical facts in areas of esoteric technology must always be supported by citation to some reference work recognized as standard in the pertinent art and the appellant given, in the Patent Office, the opportunity to challenge the correctness of the assertion or the notoriety or repute of the cited reference." *Id.* Here the Examiner bases the rejection on an unsupported statement of the level of general knowledge within the art. Applicant again invites the Examiner to provide support for the Examiner's official notice.

Additionally, Applicant also previously rebutted the Examiner's official notice, arguing that there is no motivation to modify the Hess stent to achieve the claimed subject matter, even with the Examiner's official notice (to which Applicant, did not then concede to or admit, and does not now concede to or admit is prior art). As such Applicant has requested the Examiner support the subject matter of the official notice and rebutted the finding of obviousness based on

the official notice. The Examiner's conclusion that the object of the official notice is now admitted prior art is improper.

Moreover, the Examiner improperly relies on the unsupported official notice. As the Supreme Court recently explained, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1740-41 (U.S. 2007). In that regard, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." Id. The mere fact that the prior-art reference could be modified does not satisfy the requirements for a finding of obviousness. In re Laskowski, 871 F.2d 115, 117 (Fed. Cir. 1989); In re Mills, 916 F.2d 680, 682 (Fed. Cir. 1990). There is no reason to modify the stent disclosed in Hess to obtain the claimed subject matter. And reliance on what is presumed to be the level of skill in the art is improper in the absence of a specific teaching because skill in the art cannot "act as a bridge over gaps in the substantive presentation of an obviousness case." Al-Site Corp. v. VSI Int'l, Inc., 174, F.3d 1308, 1324 (Fed. Cir. 1999). Furthermore, deficiencies in the cited reference cannot be remedied by general conclusions about what is basic knowledge. In re Lee, 277 F.3d 1338, 1345 (Fed. Cir. 2002).

Here, the Examiner has improperly concluded that the previous official notice is admitted prior art and improperly rejected the claimed subject matter by filling a gap in the disclosure of Hess with an unsupported reference to the level of common knowledge in the art. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

### Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as

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an intent to concede any issue with regard to any claim, except as specifically stated in this paper.

Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 10527-118005.

Respectfully submitted,

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